Decision Memo for Sacral Nerve Stimulation for Urge Urinary Incontinence (CAG-00058N)

Decision Summary

Medicare will cover SNS for patients with urinary urge incontinence, urgency-frequency syndrome and urinary retention. The following limitations for coverage apply to all three indications:

(1) Patient must be refractory to conventional therapy (documented behavioral, pharmacologic and/or surgical corrective therapy) and be an appropriate surgical candidate such that implantation with anesthesia can occur.

(2) The following patients are excluded: Those with stress incontinence, urinary obstruction, and specific neurologic diseases (e.g., diabetes with peripheral nerve involvement) which are associated with secondary manifestations of the above three indications.

(3) Patient must have had a successful test stimulation in order to support subsequent implantation.

(4) Patient must be able to demonstrate adequate ability to record voiding diary data such that clinical results of the implant procedure can be properly evaluated.

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Decision Memo

TO: Administrative File CAG-00058N: Sacral Nerve Stimulation

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SUBJECT: National Coverage Determination
DATE: June 29, 2001

This memo serves four purposes: (1) outlines the descriptions and treatments of urinary urge incontinence, urinary urgency-frequency syndrome and urinary retention;

(2) reviews the history of Medicare's coverage policy on sacral nerve stimulation (SNS) and provides a timeline of recent activities; (3) analyzes the relevant scientific data related to SNS; and (4) delineates the reasons for instituting a national determination to cover SNS for the management of urinary urge incontinence, urinary urgency-frequency syndrome and urinary retention.

Clinical Background

Urinary incontinence (UI) refers to the involuntary loss of urine. Approximately 13 million adults in the United States suffer from incontinence, with nearly half of nursing home residents having some degree of incontinence. For noninstitutionalized persons older than 60 years of age, prevalence ranges from 15 to 35 percent, with women having twice the prevalence of men.[1]

There are numerous causes of UI, and the following risk factors are among the most prominent:

- Immobility;
- Medications, including diuretics;
- Pelvic muscle weakness;
- Stroke; and
- Diminished cognitive status.[2]

UI has a significant impact on quality of life. Sufferers may become socially isolated due to fear of embarrassing themselves or family and friends. For example, a study by Lam et al. (1992) found that approximately 20% of incontinent women abstain from social activities due to incontinence.[3] UI is not part of the normal aging process, and it is physically and emotionally uncomfortable for the sufferer. Unfortunately, although UI is treatable, it is often left untreated. Due to social stigma associated with the disease, patients are often too embarrassed to seek help. As a result, UI is often unreported and under-diagnosed.

Types of Incontinence

There are various types of UI. The two most common types of incontinence are stress and urge incontinence. The specific diagnosis can be made by either physical examination or urodynamic testing.

- *Stress incontinence* refers to involuntary loss of urine due to inadequate urethral pressure. The patient experiences urine loss during coughing, sneezing, or physical exertion.
- *Urge incontinence* refers to the involuntary loss of urine due to abnormal bladder contractions (e.g., detrusor instability). It is often associated with a sudden, strong desire to urinate. The urge gives little warning and large amounts of urine may be lost.
- *Mixed incontinence* refers to the coexistence of both stress and urge incontinence.
- *Post-prostatectomy incontinence* refers to a common condition among elderly Medicare patients that is a result of the treatment of prostate cancer or prostatic hypertrophy. It is predominantly stress or urge.

There can also be functional incontinence, which occurs in a normal urinary tract. Such causes can be multifactorial and could include medications, infections, cancer, trauma, diverticuli and fistulas.[4]

This decision memorandum focuses on the effectiveness of SNS for the following three conditions: urge incontinence, urinary urgency-frequency syndrome and urinary retention. Each of these conditions is further discussed below:

1. Urge Incontinence

A patient with urge-incontinence is unable to hold their urine when they experience the need to urinate. Urge incontinence commonly occurs when an individual is unable to inhibit the voiding reflex. When the detrusor muscle contracts as a result of the voiding reflex, incontinence occurs if the bladder pressure exceeds the urethral closure pressure. Motor urgency, which is characterized by detrusor muscle overactivity, is the most common underlying cause of urge incontinence.

Note that specific neurologic deficits, such as stroke or multiple sclerosis, may produce such detrusor overactivity. Alternatively, idiopathic detrusor instability is a cause of urge incontinence.

2. Urinary Urgency-Frequency Syndrome

As described above, urinary urgency can be described as the sensation of needing to urinate; the patient may or may not release urine. Frequency is defined as voiding at intervals of 2 hours or less, more than 7 times per day.[5] Therefore, a patient with urinary urgency-frequency syndrome feels the need to frequently urinate throughout the day, but may not release urine. This condition can also be accompanied with urge incontinence.

Urgency-frequency syndrome may be classified into two categories: neuropathic and idiopathic, which can have implications for follow-up management. The causes of urgency-frequency are largely unknown; however, age-related causes may be a factor. For example, anatomic changes often occur with increasing age, such as a decrease in the relative volume of striated muscle and vascular component of the urethra, that may make the urethra more vulnerable to infection. Women are more likely than men to suffer from urgency-frequency syndrome.

3. Urinary Retention

Urinary retention is caused by weak bladder (detrusor) muscle contraction, a lack of bladder muscle contraction, or by obstruction resulting from urethral overactivity or mechanical outlet obstruction of the urethra, as can be seen in strictures, cancer, or benign prostatic hyperplasia. However, the precise pathophysiology causing urinary retention is often unknown, and in tandem with the above urgency disorders, constitute another portion of the spectrum of dysfunctional voiding reflexes.[6]

There is potential for numerous problems when a patient is unable to empty the bladder. Such problems include: ureteral reflux, upper urinary tract damage, and overflow incontinence. Techniques such as timed self-catheterization are used in order to drain the bladder and prevent infection.[7]

Treatments

Treatment options for the above conditions include behavioral modifications, medications, vaginal cones, electrical and magnetic stimulation, and surgery. This decision memorandum focuses solely on the use of SNS.

SNS is based on the theory that a device can stimulate the sacral nerves, which causes the bladder muscles to contract. The procedure permanently implants a device that modulates the neural pathways in order to control bladder function (the sacral nerves are vital in helping to control bladder contractions). A sacral nerve stimulator is a pulse generator about the size of a pacemaker. It is implanted in the abdominal wall and a wire lead is then attached to the sacral nerves. Electrical impulses are transmitted from the generator to the sacral nerves through the implanted wire. These impulses cause the muscles to contract, which gives the patient the ability to void.[8]

Before surgery occurs for any of the three conditions, patients are given a preliminary test in order to determine if an implantable stimulator would be effective. During this test stimulation, also known as percutaneous nerve evaluation (PNE), a wire lead is situated near the sacral nerve by achieving proper sensorimotor responses. Over the next 3-to-7 days, an external device stimulates the sacral nerves in order to cause the muscles in the bladder to contract. During this time, the patient maintains voiding diaries, and the wire is removed. The voiding diary is repeated 1 week later to make certain that the patient returns to baseline voiding. If this test is successful, as demonstrated by at least a 50% reduction in symptoms, the patient can be considered a candidate for SNS.[9]

If the test stimulation is found to be successful, the patient is then eligible for the implant procedure. The patient is placed under general anesthesia, and a midline sacral incision is made. An insulated needle is located in the appropriate foramen by evaluating neurologic responses. A quadripolar lead is placed in the foramen, and the fixed collar on the lead is sutured to the periosteum to prevent lead migration. There is a connection placed to the neurostimulator itself, which is placed into a subcutaneous pocket in the upper buttock.

History of Medicare's Coverage of SNS and Timeline of Recent Activities

- Food and Drug Administration (FDA) Approval

On September 29, 1997, Interstim SNS system, a device developed by Medtronic, Inc. (Medtronic), received FDA premarket approval (PMA) for patients with urinary urge incontinence who failed or could not tolerate more conservative treatments (e.g., pharmacologic agents). The FDA's approval came after reviewing clinical evidence and determining that the device was both safe and effective. In addition, the FDA required Medtronic to do a 5-year postmarket study of the device in order to determine its long-term safety and effectiveness. According to the FDA, "The postapproval study should assess the rates of adverse events that occurred during the 5-year follow-up period, focusing on those events which require surgical intervention, and evaluate the long-term effect of sacral nerve stimulation on urinary urge incontinence."[10] On April 15, 1999, the system received supplemental PMA approval for use in patients with urinary retention, and significant symptoms of urgency-frequency in patients who failed or could not tolerate more conservative treatments. No other implantable SNS device currently has FDA approval.[11]

- Current Coverage Issues Manual Policy

Currently, there is no national policy in place concerning SNS. Therefore, Medicare coverage is left to local contractor discretion.

- Coverage Request

The Health Care Financing Administration (HCFA) internally generated the request in January 2000 because UI is a significant problem for the Medicare population. In addition, there is significant uncertainty about alternative interventions being used to treat UI.

- Recent Developments and Timeline of Activities

January 31, 2000	HCFA internally generates a request for consideration of coverage for SNS.
February 24, 2000	Referred to Medicare Coverage Advisory Committee (MCAC) Medical and Surgical Procedures Panel, scheduled for June 14 - 15, 2000.
	Referred to the Center for Health Plans and Providers (CHPP), HCFA, for final benefit category determination.
April 12, 2000	Benefit category determination made by CHPP (§1861(s)(8) Prosthetic Device).
June 2, 2000	MCAC meeting on SNS deferred to October 18, 2000. Other incontinence issues to be addressed at the June MCAC meeting.
September 11, 2000	HCFA staff meets with Medtronic.
September 20, 2000	Health care technology assessments (TAs) (SNS and Urge Incontinence, SNS and Urgency-Frequency Syndrome), exclusion tables, and questions for October MCAC meeting posted on HCFA's web site.
September 24, 2000	HCFA receives letter from Medtronic informing of articles recently available.
October 18, 2000	MCAC Medical and Surgical Procedures Panel meeting on SNS held.
December 1, 2000	Manuscript (accepted for publication)[12] concerning SNS for patients with urinary retention sent to HCFA by Medtronic.
February 22, 2001	Executive Committee (EC) of the MCAC meets to ratify the recommendations of the Medical and Surgical Procedures Panel.
May 1, 2001	EC recommendation officially received by HCFA.

Summary of Evidence

In gathering information concerning two of the three indications for SNS, urge urinary incontinence and urgency-frequency syndrome, we relied heavily on two TAs performed by the Blue Cross/Blue Shield (BC/BS) Technology Evaluation Center.[13] In addition, we reviewed six case series published on urge incontinence identified through a combination of a Medline search and receipt of such articles from Medtronic. The data in these articles were omitted from the TA, given the much stronger data available from a randomized clinical trial. Further, no supplemental literature was available for the urgency-frequency syndrome. It is important to note that there was no TA conducted on retention, which is the third indication considered in this memorandum. In discussing SNS with BC/BS staff, we learned that a TA was not done on retention during this time period because the article evaluating retention patients from the clinical trial had not yet been published. The article was later published in The Journal of Urology in January 2001, making it possible for HCFA staff to include it in our analysis and this decision memorandum.

The primary evidence reviewed was derived from one prospective, randomized study[14] supported by Medtronic. This worldwide study was conducted in 16 centers in the United States, Canada and Europe. Study candidates were selected from the general gerontological population and were qualified according to baseline screening criteria, which included: medical history, urodynamic testing, and quantification of voiding behavior through diaries. Table 1 includes additional information about the trial and each of the three patient populations evaluated.

Patients eligible for the study were required to meet specified inclusion and exclusion criteria (see Table 1). Incorporated in these criteria is the stipulation that patients must be refractory to standard medical therapy, which includes pelvic muscle exercises, pharmacological therapy, and surgical correction procedures such as augmentation cystoplasty. These patients were assessed during a 3-to-7 day trial period (via PNE described above), in order to determine whether they would be viable candidates for permanent implantation of the stimulator device. This test was necessary in order to quantify the effects of stimulation on dysfunctional voiding behavior. During the trial period, voiding behavior was documented in a diary. Patients were found to be qualified for surgical implantation if they demonstrated greater than 50% improvement in baseline voiding during test stimulation. These patients were randomized to either the treatment (immediate implantation) group or control (delayed implantation) group.

The treatment group received surgical implantation of the SNS system. The control group received standard medical treatment, which included both pharmacologic and surgical interventions. Standard treatment was provided for 6 months, at which time the controls were given the option of crossing over and receiving the surgical implant, if they met pre-specified criteria (e.g., good surgical candidate). After implantation, the treatment group was evaluated at 1, 3 and 6 months, and then every 6 months for 12-to-24 months (see Table 1 for drop-out rates). Six-month voiding diaries were compared between the two groups. The treatment group was also assessed through a therapy evaluation test. During this test, the system was deactivated for a minimum of 3 days, and voiding behavior was recorded. Stimulation was reactivated after this period. Patients served as their own controls, and voiding behavior with and without SNS was compared.

The results from each of the three stimulation groups (urge incontinence, urgency- frequency syndrome and urinary retention) were more favorable when compared to the controls. The results reflecting each condition are reported below:

1. Urinary urge incontinence (Schmidt, et al. 1999)

Efficacy was based upon the 98 patients who successfully completed test stimulation. At 6 months, there was a significant reduction in urge incontinence symptoms for the treatment group in comparison to the control group. The treatment group had fewer daily incontinence episodes; 47% of these patients were completely dry at 6 months. After 6 months of treatment, three patients had no reduction in incontinence: one patient was explanted due to pain, and the remaining two experienced an increase in frequency. In addition to a lower number of daily incontinence episodes, the treatment group also experienced episodes of less severity. For the treatment group at baseline, there was an average of 3.4 +/- 3.8 daily, heavy incontinent episodes.

Six months after implantation, this number in the treatment group decreased to 0.3 +/- 0.9. For the control group at baseline, there was an average of 2.6 +/- 3.5 heavy episodes. After six months of conservative treatment, this number increased to 3.9 +/- 3.8. Six months after implantation, patients were assessed by a therapy evaluation test. Once stimulation was deactivated, the average frequency of daily incontinence episodes increased from 2.9 to 9.5. The average severity ranking of leaks increased from 0.8 to 1.9. Of the 28 patients in the treatment group compared to 32 patients in the control group, there was no significant difference in the mental health component of the SF-36 Health Survey. The treatment group did, however, show a favorable change in their perceptions of physical health compared to those in the control group.

2. Urgency-frequency syndrome (Hassouna, et al. 2000)

Efficacy was based on the 51 patients who successfully completed test stimulation. At 6 months, there was a significant reduction in the number of daily voids in the treatment group when compared to the control group. Voids in the treatment group decreased from 16.9 +/- 9.7 at baseline to 9.3 +/- 5.1 6 months after implantation. The number of voids did not change in the control group over this 6-month period. It is important to note that patients who exhibited more than seven voids daily at baseline were considered to have a successful clinical outcome if they voided 4-to-7 times daily or reduced the number of voids by at least 50%. Fifty-six percent (14/25) of the treatment group demonstrated a successful clinical outcome. Eight percent (2/25) demonstrated no reduction, or an increase in the number of daily voids at 6 months. However, according to voiding diaries, these patients demonstrated improvement at 12 months. One patient was explanted due to therapy-related bowel dysfunction.

There was also demonstrated benefit in the volume voided and degree of urgency before voiding in the treatment group in comparison to the control group. At baseline, the treatment group experienced an average of 118 +/- 74 ml. voided volume per void. At 6 months, this amount significantly increased to 226 +/- 124 ml. The control group did not demonstrate a significant change (from 124 +/- 66 ml. at baseline to 123 +/- 75 ml. 6 months later). With respect to the degree of urgency before voiding, the treatment group decreased from 2.2 +/- 0.6 at baseline to 1.6 +/- 0.9 6 months after implantation. There was little change in the control group over 6 months, since at baseline the mean was 2.4 +/- 0.5, and at 6 months was 2.3 +/- 0.5.

Twenty-two of the twenty-five treatment patients underwent the therapy evaluation test. One patient was explanted and two refused to have the stimulator inactivated for fear of returning symptoms. The average number of voids per day increased from 8.6 to 13.9, and voided volume per void decreased from 242ml to 144 ml. In addition, results from the SF-36 Health Survey demonstrated that the treatment group compared to the control group experienced quality of life improvements in physical function, bodily pain, general health, vitality, social function and mental health.
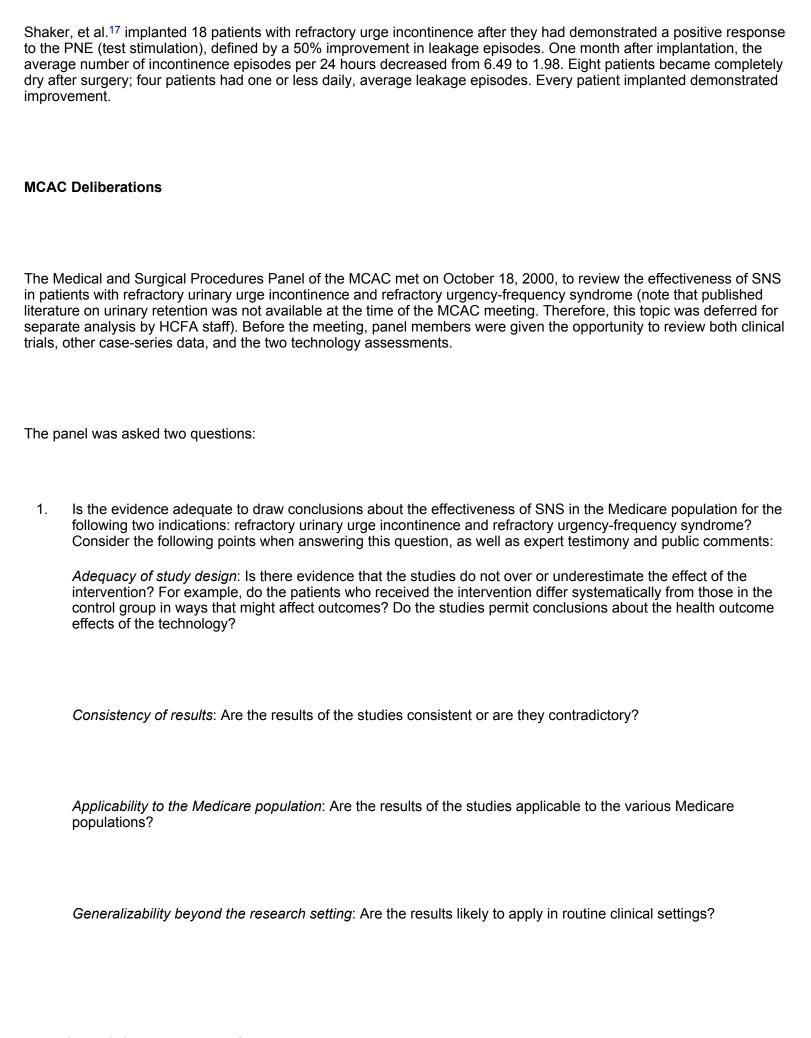
3. Urinary retention (Jonas, et al. 2001)

Sixty-eight of the one hundred seventy-seven patients were eligible for implantation via test stimulation. Of these patients, efficacy at 6 months was evaluated for those in the treatment (29) and control (22) groups. Of the remaining 17 patients, 6 were not yet enrolled in the study for 6 months, 3 had been lost to follow-up, and 8 were included in the study but did not submit a voiding diary. The catheter volume significantly decreased for the treatment group from a baseline 339 +/- 176 ml. to 49 +/-106 ml. at 6 months after implantation. The baseline for the control group was 350 +/- 152 ml., compared to 319 +/-195 6 months later. The number of catheterizations also decreased for the treatment group from 5.7 +/- 3.1 at baseline to 1.4 +/- 2.6 at 6 months. There was little change for the control group, since at baseline the number of catheterizations was 4.0 +/- 1.7, and at 6 months was 3.9 +/- 2.2. The treatment group demonstrated an increase in the number of voids per day from 4.0 +/- 4.9 at baseline, to 6.5 +/- 3.1 6 months later. The control group voided an average of 3.2 +/- 4.1 at baseline, and 2.9 +/- 4.3 6 months later.

Thirty-four patients (including those who crossed over from the control group) completed the therapy evaluation test. Nine patients refused to take the test for fear of experiencing recurring symptoms. Once the system was inactivated, all 34 patients had an increase in residual urine and a decrease in volume voided.

Non-clinical trial articles (see Attachment 3)

The six case series articles reviewed demonstrate significant improvements due to SNS for similar patient populations. The data was largely collected in the same manner as in the clinical trial: patients were required to pass a pre-test stimulation before they were eligible for surgical implantation. Representative studies are discussed. For example, Bosch, et al.[15] recruited 85 patients with refractory urge incontinence and 45 patients responded to test stimulation. Forty percent (18/45) of the implanted patients were considered cured. Cure was defined as more than 90% improvement in pad use and/or incontinence episodes. Twenty percent (9/45) exhibited partial success. Partial success was defined as a 50%-to-90% decrease in pad use and/or incontinence episodes. Eighteen (40%) patients failed due to technical problems, such as lead breakage and electrode dislocation.

Elabbaddy, et al[16] studied 50 patients with various forms of voiding dysfunction, of which 17 had a satisfactory response to PNE and exhibited a 70% or greater improvement in symptoms. These individuals were divided into two groups: group one included eight patients who presented with chronic urinary retention and group two included nine patients who presented with other forms of voiding dysfunction, such as frequency and urgency. Everyone in group one showed increased mean, voided volume after implantation from 25.9 +/- 7.1% to 81.1 +/-6.7%. In group two, frequency improved by 73%, urgency improved by 42%, and leaking episodes and numbers of diapers per day decreased by 50%.

Shaker, et al.[17] implanted 18 patients with refractory urge incontinence after they had demonstrated a positive response to the PNE (test stimulation), defined by a 50% improvement in leakage episodes. One month after implantation, the average number of incontinence episodes per 24 hours decreased from 6.49 to 1.98. Eight patients became completely dry after surgery; four patients had one or less daily, average leakage episodes. Every patient implanted demonstrated improvement.

MCAC Deliberations

The Medical and Surgical Procedures Panel of the MCAC met on October 18, 2000, to review the effectiveness of SNS in patients with refractory urinary urge incontinence and refractory urgency-frequency syndrome (note that published literature on urinary retention was not available at the time of the MCAC meeting. Therefore, this topic was deferred for separate analysis by HCFA staff). Before the meeting, panel members were given the opportunity to review both clinical trials, other case-series data, and the two technology assessments.

The panel was asked two questions:

1. Is the evidence adequate to draw conclusions about the effectiveness of SNS in the Medicare population for the following two indications: refractory urinary urge incontinence and refractory urgency-frequency syndrome? Consider the following points when answering this question, as well as expert testimony and public comments:

    Adequacy of study design: Is there evidence that the studies do not over or underestimate the effect of the intervention? For example, do the patients who received the intervention differ systematically from those in the control group in ways that might affect outcomes? Do the studies permit conclusions about the health outcome effects of the technology?

    Consistency of results: Are the results of the studies consistent or are they contradictory?

    Applicability to the Medicare population: Are the results of the studies applicable to the various Medicare populations?

    Generalizability beyond the research setting: Are the results likely to apply in routine clinical settings?

2. If the evidence is adequate to draw conclusions, what is the size, if any, of the overall health effect of SNS, compared with alternative treatments for refractory cases? These alternatives tend to be surgical. Place size and direction of effectiveness into one of the following seven categories:

Breakthrough technology: The improvement in health outcomes is so large that the intervention becomes standard care.

More effective: The new intervention improves health outcomes by a significant, albeit small, margin as compared with established services or medical items.

As effective but with advantages: The intervention has the same effect on health outcomes as established services or medical items but has some advantages (convenience, rapidity of effect, fewer side effects, other advantages) that some patients will prefer.

As effective and with no advantages: The intervention has the same effect on health outcomes as established alternatives but with no advantages.

Less effective but with advantages: Although the intervention is less effective than established alternatives (but more effective than doing nothing), it has some advantages (such as convenience, tolerability).

Less effective and with no advantages: The intervention is less effective than established alternatives (but more effective than doing nothing) and has no significant advantages.

Not effective: The intervention has no effect on or has deleterious effects of health outcomes when compared with "doing nothing," (e.g., treatment with placebo or patient management without the use of a diagnostic test).

After hearing comments from the public in addition to public testimony, the panel asked numerous questions. It was explained that at the time the two assessments were performed, the retention data was not published. The panel also questioned the definition of refractory and found it would be reasonable to draw the conclusion that refractory referred to failed pharmacologic treatment and/or behavioral therapy. In addition, the panel spent time discussing Medtronic's training program, which is mandated by the FDA.

In answering Question 1, the panel unanimously agreed there is adequate evidence to draw conclusions about the effectiveness of SNS in the Medicare population for refractory urinary urge incontinence and refractory urgency frequency syndrome. With respect to Question 2, there was unanimous agreement that SNS was more effective than alternative treatments.
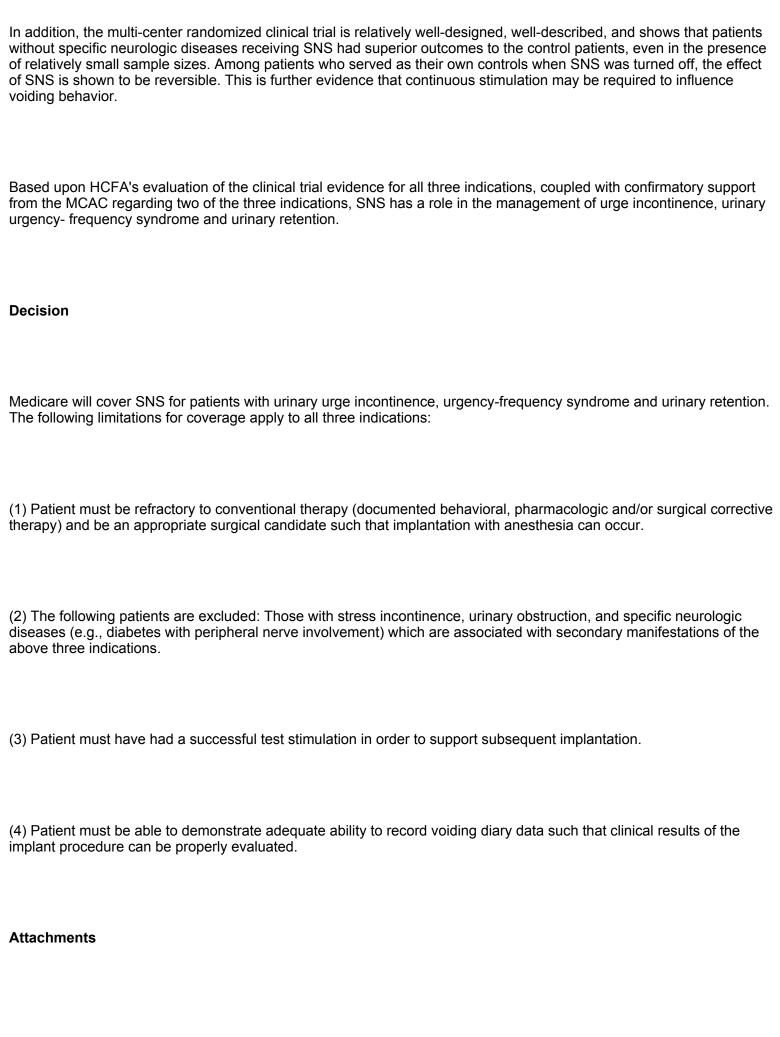
HCFA Analysis

In analyzing the clinical trial and additional journal articles, HCFA staff had numerous concerns. One such concern is that the efficacy rates reported in the three peer-reviewed articles (which reflect the clinical trial) are somewhat misleading. Efficacy was based exclusively on the patients who successfully completed test stimulation. To be more specific, 155 patients with urinary urge incontinence, as reported in Schmidt, et al[18], were originally enrolled in the study. Of these patients, 57 did not demonstrate significant improvement during the test stimulation, and were therefore not randomized into the study. Instead of surgically implanting patients who may experience no improvement, the test stimulation gives a physician insight into the level of response a patient may experience. We believe that the pre-test is a critical component of the SNS system.

Another consideration is that most of the patients in the randomized trial did not reflect the Medicare population. Mean ages of the patients in the trial were considerably below age 65. It is, therefore, impossible to express complete certainty that Medicare patients will benefit from SNS. However, BC/BS also considered this issue in both TAs and concluded that, "There are no physiologic reasons to expect that elderly patients will respond differently, and there is no evidence to suggest that efficacy of treatment for urge incontinence/ urgency-frequency differs according to age."[19][20]

A third concern raised by HCFA staff is the large drop-out rates in the clinical trial. This is specifically relevant to the patients in the urge incontinence and retention treatment groups. The urge incontinence test group/control group drop-out rates were 34.6/8.7%. The urinary retention test group/control group drop-out rates were 21.6/29.0%. For urge incontinence, the drop-outs were accounted for via sequential data analysis; therefore, this was less of a concern. In contrast, the urinary retention study, with its 25% drop-out rate (17/68) reported no such adjustment. This raised concerns about potentially significant bias, since it is possible that these lost patients included a disproportionate number of treatment failures.

Despite these shortcomings in the quality of available evidence, we continue to believe that SNS is a beneficial treatment for patients who have tried alternatives, such as bladder training and pharmacologics, without relief. Voiding difficulty is a substantial problem in the United States, and the patients affected can be difficult to treat. Such conditions have a negative impact on quality of life, leading patients to depression and solitude.

In addition, the multi-center randomized clinical trial is relatively well-designed, well-described, and shows that patients without specific neurologic diseases receiving SNS had superior outcomes to the control patients, even in the presence of relatively small sample sizes. Among patients who served as their own controls when SNS was turned off, the effect of SNS is shown to be reversible. This is further evidence that continuous stimulation may be required to influence voiding behavior.

Based upon HCFA's evaluation of the clinical trial evidence for all three indications, coupled with confirmatory support from the MCAC regarding two of the three indications, SNS has a role in the management of urge incontinence, urinary urgency- frequency syndrome and urinary retention.

Decision

Medicare will cover SNS for patients with urinary urge incontinence, urgency-frequency syndrome and urinary retention. The following limitations for coverage apply to all three indications:

(1) Patient must be refractory to conventional therapy (documented behavioral, pharmacologic and/or surgical corrective therapy) and be an appropriate surgical candidate such that implantation with anesthesia can occur.

(2) The following patients are excluded: Those with stress incontinence, urinary obstruction, and specific neurologic diseases (e.g., diabetes with peripheral nerve involvement) which are associated with secondary manifestations of the above three indications.

(3) Patient must have had a successful test stimulation in order to support subsequent implantation.

(4) Patient must be able to demonstrate adequate ability to record voiding diary data such that clinical results of the implant procedure can be properly evaluated.

Attachments

1. SNS for the treatment of refractory urge incontinence. HCTA

2. SNS for the treatment of urinary urgency/frequency in adults. HCTA

3. Literature Review for Case-Series Studies on Urinary Urge Incontinence

4. Bibliography

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[1] AHCPR publication No. 96-0686. 1992

[2] AHCPR publication No. 96-0683. 1996

[3] Lefevre, March 2000

[4] Resnick, et al. 1985

[5] Lefevre, August 2000

[6] Jonas, et al. 2001

[7] Jonas, et al. 2001

[8] Snider, 1997

[9] Hassouna, et al. 2000, Jonas et al. 2001, Schmidt et al. 1999

[10] FDA Memorandum P970004. 1997

[11] Lefevre, March 2000

[12] Jonas, et al. 2001

13 It is notable that pre-publication material concerning the clinical trial was provided by Medtronic, Inc. to BC/BS in preparation for these assessments.

14 It is notable that the clinical trial generated peer-reviewed publications on each of three conditions: urge incontinence (Schmidt, et al.), urgency-frequency syndrome (Hassouna, et al.) and urinary retention (Jonas, et al.).

15 Bosch, et al. 2000

16 Elabbady, et al. 1994

17 Shaker, et al. 1998

18 Schmidt, et al. 1999

19 Lefevre, March 2000

20 Lefevre, August 2000

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